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| APPLICATION NO.   | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                  | CONFIRMATION NO. |
|---|----------------|----------------------|--------------------------------------|------------------|
| 09/723,459  | 11/28/2000     | Gopinathan K. Menon  | 680.0041USU                          | 6235             |
| 7:  | 590 04/17/2002 |                      |                                      |                  |
| Charles N.J. Ruggiero, Esq.   |                |                      | EXAMINER                             |                  |
| Ohlandt, Greeley, Ruggiero & Perle, L.L.P. 10th Floor One Landmark Square |                | .Р.                  | OSTRUP, CLINTON T  ART UNIT PAPER NU |                  |
|   |                |                      |                                      |                  |
| Stamford, CT  | 06901-2682     |                      | 1614                                 |                  |
|   |                |                      | DATE MAILED: 04/17/2002              | <b>Y</b>         |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | Applicati n No.  | Applicant(s)   |  |  |  |
|---|--|--|--|--|--|--|
| Office Action Summary   |  | 09/723,459   | MORELLI-ABRAMS ET AL.  |  |  |  |
|   |  | Examiner   | Art Unit   |  |  |  |
|   |  | Clinton Ostrup   | 1614   |  |  |  |
| Period fo   | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |  |  |  |
| THE - Exte after - If the - If NC - Failu - Any   | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period treeto reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing ad patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply to the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS a, cause the application to become ABAND | be timely filed ) days will be considered timely. from the mailing date of this communication. ONED (35 U.S.C. & 133). |  |  |  |
| 1)  | Responsive to communication(s) filed on  | ·  |  |  |  |  |
| 2a)□  | This action is FINAL. 2b)⊠ TI  | nis action is non-final.   |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  |  |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1,3-13 and 15-28</u> is/are pending in the application.   |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1,3-13 and 15-28</u> is/are rejected.   |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |  |  |  |  |  |  |
| 8)□   | 8) Claim(s) are subject to restriction and/or election requirement.  |  |  |  |  |  |
| Application Papers  |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.  |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |  |  |  |  |  |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.   |  |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |  |  |  |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |  |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |  |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |  |  |  |  |  |  |
|   | 1. Certified copies of the priority documents have been received.  |  |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No   |  |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |  |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |  |  |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |  |  |  |  |  |  |
| Attachment(s)   |  |  |  |  |  |  |
| 2) Notice 3) Inform   | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)  | 5) Notice of Inform  | nary (PTO-413) Paper No(s)<br>nal Patent Application (PTO-152)   |  |  |  |
| J.S. Patent and Tra<br>PTO-326 (Rev   | . 04.04  | etion Summary  | Part of Paper No. 8  |  |  |  |

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### **DETAILED ACTION**

Claims 1, 3-13, and 15-28 are pending in this application.

#### Irradiated Mail

The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date

Certificate of Mailing Date

January 18, 2002

January 2, 2002

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

# COPY OF PAPERS ORIGINALLY FILED

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within THREE MONTHS of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record

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of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (i.e., the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

# Response to Amendments and Arguments 35 USC § 112, First Paragraph

Applicant's amendment's and arguments filed January 18, 2001, Paper No. 7, to the rejection of claims 15-21 under 35 U.S.C. 112, first paragraph have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

## 35 USC § 112, Second Paragraph

Applicant's amendment's and arguments filed January 18, 2001, Paper No. 7, to the rejection of claims 3, 8, 11-12, 20-21, and 24 under 35 U.S.C. 112, second paragraph have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

# 35 USC § 102

The rejection of claims 1, 3-6, 8 and 22-26 under 35 US.C. 102 (b) as being unpatentable over MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO, JP 07138135A, is MAINTAINED for the reasons set forth in the Office Action mailed October 01, 2001 and those found below.

In response to applicant's arguments, the recitation that the instant composition is being used to improve the aesthetic appearance of skin, scalp, and /or hair, has not been given patentable weight in the composition claims because the recitation occurs in

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the preamble of composition claims. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that the '135 reference is drawn to a hair growth composition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's argument that the method claims of 22, 23 and 25 are methods drawn to increasing the aesthetic appearance of skin, scalp, and/or hair, claim 23 describes the improvement in aesthetic appearance of hair as including, increasing hair growth. Thus the '135 reference clearly anticipates instant claims 22-23. The '123 reference teaches the 50 % ethanol extract as being present in a lotion preparation in an amount of 0.5 weight percent, thus teaching the specific amounts of instant claims 1, 3, and 24.

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The rejection of claims 1, 3-6, and 8 under 35 US.C. 102 (b) as being unpatentable over MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO, JP 07126143A, is **MAINTAINED** for the reasons set forth in the Office Action mailed October 01, 2001 and those found below.

Applicant argues that the '143 reference discloses the concentration of the crape myrtle extract to be 50% of the total composition. However, applicant is in error. The '143 reference teaches using a 50% ethanol extract solution of Lagerstroemia speciosa in an amount of 1.0 weight percent to prepare a lotion. Thus the '143 reference clearly anticipates instant claims 1, 4-6, and 8.

#### 35 USC § 103

The rejection of claims 1 and 3-9 under 35 US.C. 103 (a) as being unpatentable over MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO, JP 07126143A and further in view of Soudant et al **5,916,579**, is **MAINTAINED** for the reasons set forth in the Office Action mailed October 01, 2001 and those found below.

Applicant argues that the '143 reference does not teach the specific percentages as claimed instantly in amended claim 1 and that the combination of references does little to alleviate the failure of the '143 reference to disclose applicant's invention.

However, applicant is not correct. The translation of the '143 reference clearly reveals the amounts of the ethanol extract of Lagerstroemia speciosa in a lotion as being 0.5 weight percent of the preparation.

Therefore, it would have been obvious to one having ordinary skill n the art at the time the invention was made to have modified the skin whitening cosmetic lotion

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preparation of '143 by adding the conventional cosmetic additives as taught by Soudant et al., because of the reasonable expectation of obtaining a skin whitening lotion capable of being applied to the skin daily comprising additives for their art recognized purpose.

The rejection of claims 1, 3-9, and 22-27 under 35 US.C. 103 (a) as being unpatentable over MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO, JP 07138135A and further in view of Abe et al **4,839,168**, is **MAINTAINED** for the reasons set forth in the Office Action mailed October 01, 2001 and those found below.

Applicant argues that the '135 reference does not teach the percentage of the extract claimed in independent claim 1, and that the combination of the '135 reference and the Abe reference does not render the Applicant's invention obvious. Applicant further argues that the combination of references amounts to hindsight reconstruction of the present invention, as Abe does not include the crape myrtle extract.

The examiner respectfully disagrees. The '135 reference teaches the 50 % ethanol extract as being present in a lotion preparation in an amount of 0.5 weight percent, thus teaching the specific amounts of instant claims 1, 3, and 24, as discussed above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

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the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both reverences are drawn to hair care cosmetics comprising plant extracts. Abe et al., describe the specific plants in their application as examples of the plants which may be used and teach other ingredients, such as UV absorbers and antioxidants as useful in hair care compositions. The '135 reference teaches hair treating compositions comprising the specific plant extract Lagerstroemia speciosa and describes these compositions as having an excellent hair restoring effects.

Since claim 23 describes the improvement in the aesthetic appearance of hair as including increasing the rate of hair growth, hair thickness, and overall hair health, the combination of the '135 reference and the Abe reference clearly make these and the other aesthetic hair improvements of instant claims 22-27 obvious.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of '135 by adding the specific "other ingredients" as taught by Abe et al., because of the expectation of obtaining a hair growth composition in a lotion form with known cosmetic additives added for their art recognized purpose.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claims 15-17, and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by MIKIMOTO PHARMACEUT CO LTD, JP 2000-072649, based on the Derwent abstract provided.

The '649 reference teaches an elastase inhibitor for maintaining elastic texture and youthfulness of skin comprising a mixture of plant extracts, including Lagerstroemia speciosa leaf extract. The reference teaches that the elastase inhibitor is used for applying to the skin and that it is very effective and safe for reducing wrinkles and providing glow to the skin. See: abstract.

#### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-13, 15-21 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over MIKIM TO PHARMACEUT CO LTD, JP 2000-072649, as applied to claims 15-17 above, and further in view of by MIKIMOTO Pharmaceutical CO LTD NANBA TSUNEO JP 07126143 A and Soudant et al 5,916,579.

JP 2000-072649 teaches an elastase inhibitor for maintaining elastic texture and youthfulness of skin comprising a mixture of plant extracts, including Lagerstroemia speciosa leaf extract. The reference teaches that the elastase inhibitor is used for applying to the skin and that it is very effective and safe for reducing wrinkles and providing glow to the skin. However, the primary reference does not specifically teach the amount of extract of instant claims 1, 3, 11-12, 10-21 and the cosmetic additives of instant claims 6-7, and 9.

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The 07-126143 reference describes a cosmetic for whitening the skin, which contains an extract of *Lagerstroemia speciosa*. The reference teaches using the extract to prepare conventional cosmetics such as lotions, creams, emulsions, and packs using known additives and carriers. Claim 8 would be inherently met by the reference, because colosolic acid is in the extract of *Lagerstroemia speciosa*. See: abstract.

Soudant et al disclose a treatment and/or prevention of the problems of adiposity and compositions which may be used for combating it. The reference describes the need for a composition which may be applied topically because the other methods which have been proposed for treating adiposity involve surgical methods which are invasive, risky, and expensive. See: col. 1, line 58 – col. 2, line 35.

The compositions which may be in the form of lotions, emulsion, gels, creams, etc. are taught to contain conventional additives such as UV screening agents, thickening agents alph-hydroxy acids, preservative agents, and in general, all the excipients usually found in the field of Pharmacopoeia. Further, the secondary reference teaches that compositions may contain plant extracts in amounts which overlap those of instant claims 2-3. See: col. 4, line 19 – col. 5 line 29. Moreover, the secondary reference teaches applying the composition on a daily basis and in amounts which vary depending on the concentration and agents chosen. See: col. 5, lines 30-61.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the wrinkle treatment formulation of JP 2000-072649 by adding the amounts of extract of *Lagerstroemia speciosa* as taught in the

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skin whitening cosmetic formulation of 07-126143 and by adding the conventional cosmetic ingredients as taught by Soudant et al because of the expectation of obtaining a skin treatment composition capable of being applied to the skin daily which would have a therapeutic wrinkle reducing and whitening effect with known cosmetic additives added for their art recognized purpose.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

> Clinton Ostrup Examiner Art Unit 1614

April 11, 2002